IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicants	:	Yuki ABE et al.
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For	:	METHODS FOR PRODUCING ML-236B, A PRAVASTATIN PRECURSOR, USING A HOST CELL TRANSFORMED WITH *mlcR*, A TRANSCRIPTION FACTOR
Art Unit	:	1652
Examiner	:	Kathleen M. Kerr
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DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
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ATTENTION: MAIL STOP AMENDMEMT

S I R :

The undersigned declares as follows:

1. I am a coinventor of the above-identified patent application.

2. I graduated from the University of Tokyo in the year 1994, and I received the degree of Ph.D.

3. I have worked for Sankyo Company, Limited of Tokyo, Japan, since the year 1996, and I presently hold the position of a scientist.

4. With regard to Yu et al., Applied and Environmental Microbiology, (1995), 61(6), 2372-2377, which was applied in a prior art rejection in the July 15, 2004 Office Action, I carried out an analysis of the homology between *Aspergillus parasiticus aflR* and *Aspergillus flavus AflR*, and *Penicillium citrinum mlcR* (as in the present invention) using DNASIS software. The results of such analysis are set forth in the following Tables 1 and 2.

Table 1 cDNA sequence homology between *mlcR* and *aflR*

			Homology(%)
cDNA sequence	*mlcR*	*A. parasiticus aflR*	*A. flavus aflR*
Penicillium citrinum mlcR	100	no homology	no homology
Aspergillus parasiticus aflR	no homology	100	96.9
Aspergillus flavus aflR	no homology	96.9	100

Table 2 Amino acid sequence homology between MlcR and AflR

			Homology(%)
Amino Acid sequence	MlcR	*A. parasiticus* AflR	*A. flavus* AflR
Penicillium citrinum MlcR	100	no homology	no homology
Aspergillus parasiticus AFLR	no homology	100	94.2
Aspergillus flavus AFLR	no homology	94.2	100

The above results show that the cDNA (nucleotide) homology between the two *aflR* genes is 96.9%, and the amino acid homology between the two *aflR* genes is 94.2%. The above results also demonstrate that the *mlcR* gene reveals no homology with both *aflR* genes.

5. Regarding WO 01/12814 which was applied with Yu et al. in a prior art rejection in the July 15, 2004 Office Action, in the specification of WO 01/12824, it was shown that a gene cluster containing six hypothetical genes could enhance the production of ML-236B. But it was not shown which gene or which combination of genes could really work and enhance said production.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: Oct 6 , 2004 By: Yuki Abe

Name: 阿部有生